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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/039,307 | 10/26/2001 | Michael R.S. Hill | P-8969.00 | 2140 |

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| EXAMINER | |
|---|---|
| OROPEZA, FRANCES P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/039,307 | HILL ET AL. | |
| | Examiner | Art Unit | |
| | Frances P. Oropeza | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response*

1. The Applicant amended at least the independent claims in the response file 12/7/05, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-27 and 30-32 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find the limitation in quotations, "mammalian" ventricular dysfunction, in the original specification. New matter may not be added at this point in the process. Appropriate correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1-27, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague because it is unclear if the invention focuses on imbalance of the endocrinological system as noted in the preamble, or if it focuses on imbalances of the neuro-endocrinological system as noted in the body of the claim.

Claim 17 is vague because it is unclear if the invention focuses on imbalance of the endocrinological system as noted in the preamble, or if it focuses on imbalances of the neuro-endocrinological system as noted in the body of the claim.

Claim 29 is vague because it is unclear if the invention focuses on imbalance of the neuro-endocrinological system as noted in the preamble, or if it focuses on imbalances of the endocrinological system as noted in the body of the claim.

Claim 30 is vague because it is unclear if the invention focuses on imbalance of the neuro-endocrinological system as noted in the preamble, or if it focuses on imbalances of the endocrinological system as noted in the body of the claim.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

6. Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Levine et al. (US 6058328).

Obel et al. disclose an implantable electrical nerve stimulator/ pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic vertebra T2

providing electrical communication and the stimulation coordinated with the heart to provide resynchronization therapy (abstract; col. 1 @ 15-24; col. 3 @ 8-28 & 42-45; col. 3 @ 62 – col. 4 @ 26; col. 5 @ 25-64). Anti-tachycardia pacing may be incorporated (col. 9 @ 53 – col. 10 @ 2). Ventricular dysfunction, heart failure, imbalance of the autonomic tone, imbalance of the endocrinological system and imbalance of the neuro-endocrinological system are recognized to be disease conditions that are often cluster in being that have compromised cardiac systems. Cardiac disease associated with the loss of vagal tone is treated automatically using neural stimulation (col. 1 @ 9-13; col. 5 @ 3-18). Obel et al. teach the inclusion of tachycardia pacing therapies to treat arrhythmias that accompany the lost of vagal tone and arrhythmias that are not treated by vagal stimulation alone (col. 5 @ 3-16; col. 6 @ 66 – col. 7 @ 4; col. 9 @ 53 - col. 10 @ 2).

As discussed in the previous paragraph of this action, Obel et al. disclose the claimed invention except for delivering overdrive pacing.

Levine et al. teach preemptive tachyarrhythmia pacing using overdrive pacing in conjunction with the treatment of vagal tone for the purpose of minimizing the likelihood of the occurrence of tachyarrhythmia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used overdrive pacing in the Obel et al. system in order to prevent the occurrence of a tachyarrhythmia (abstract; col. 1 @ 11-19; col. 36 @ 11-20).

7. Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) (US) in view of Bennett et al. (US 5213098).

Obel et al. disclose an implantable electrical nerve stimulator/ pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic vertebra T2 providing electrical communication and the stimulation coordinated with the heart to provide resynchronization therapy (abstract; col. 1 @ 15-24; col. 3 @ 8-28 & 42-45; col. 3 @ 62 – col. 4 @ 26; col. 5 @ 25-64). Anti-tachycardia pacing may be incorporated (col. 9 @ 53 – col. 10 @ 2). Ventricular dysfunction, heart failure, imbalance of the autonomic tone, imbalance of the endocrinological system and imbalance of the neuro-endocrinological system are recognized to be disease conditions that are often cluster in being that have compromised cardiac systems. Cardiac disease associated with the loss of vagal tone is treated automatically using neural stimulation (col. 1 @ 9-13; col. 5 @ 3-18). Obel et al. teach the inclusion of tachycardia pacing therapies to treat arrhythmias that often accompany the lost of vagal tone and arrhythmias that are not treated by vagal stimulation alone (col. 5 @3-16; col. 6 @ 66 – col. 7 @ 4; col. 9 @ 53- col. 10 @ 2).

As discussed in the previous paragraph of this action, Obel et al. disclose the claimed invention except for delivering overdrive pacing.

Bennett et al. teach cardiac pacing using post-extra systolic potentiation (PESP) for the purpose of reducing the risk of arrhythmias. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used post-extra systolic potentiation in the Obel et al. system in order to prevent potentially life threatening arrhythmias from occurring (abstract; col. 1 @ 8-13).

8. Claims 3, 19, and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Levine et al. (US 6058328) and further in view of Adams (US 57992187). As discussed in paragraph 6 of this action, modified Obel et al. disclose the claimed invention except for the driver circuit delivering high-voltage stimulation (claim 39), and the electrode located external to the patient's body (claims 3 and 19).

As to delivering high voltage stimulation, Adams teaches cardiac arrhythmia treatment using cardioversion/ defibrillation shock therapy for the purpose of converting dysrhythmia to normal sinus rhythm. It would have been obvious to one having ordinary skill in the art at the 39*time of the invention to have used high voltage stimulation in the modified Obel et al. system in order to offer a proven alternate treatment for arrhythmias so the dysrhythmia is effectively treated before the patient suffers any ill effects from the dysrhythmia (col. 3 @ 1-8).

As to the electrode being located external to the patient's body, Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the modified Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension and anxiety is controlled (abstract; col. 2 @ 48-55; col. 3 @ 1-8 & 45-48; col. 7 @ 11-24). It is noted both electrical and electromagnetic pain suppression systems are well know in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be ab obvious design choice.

9. Claims 14, 35 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Levine et al. (US 6058328) and further in view of Sweeney et al. (US 6272377). As discussed in paragraph 6 of this action, modified Obel et al. disclose the claimed invention except for the electrode being located on an intrinsic cardiac ganglia (claims 14, 35) and providing a drug delivery device with agent (claim 40).

Sweeney et al. teach arrhythmia treatment using drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) for the purpose of preventing the development of an arrhythmia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) in the modified Obel et al. system in order to provide alternate proven means to prevent or reduce the consequences of the arrhythmia (abstract; col. 4 @ 61 – col. 5 @ 5; col. 8 @ 49-55).

*Specification*

10. The amendment filed 12/7/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: as noted in quotations, "mammalian" ventricular dysfunction.

Applicant is required to cancel the new matter in the reply to this Office Action.

11. The status of the cases on page 1 of the specification needs to be updated.

*Statutory Basis*

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
3/5/06

Robert E. Pezzuto
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